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Translation

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>D3-A0208P</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/JP2004/000957</b>	International filing date (day/month/year) <b>30.01.2004</b>	Priority date (day/month/year) <b>19.02.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>C12N 15/86, 15/861, 5/10, A61K 48/00, A61P 9/10</b>		
Applicant <b>DNAVEC RESEARCH INC.</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

- a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
  - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
  - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))

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related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- |                                     |              |                                                                                                                                                                 |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report                                                                                                                                             |
| <input type="checkbox"/>            | Box No. II   | Priority                                                                                                                                                        |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability                                                                |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention                                                                                                                                      |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited                                                                                                                                         |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application                                                                                                                |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application                                                                                                           |

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPRA/	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000957

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
  - ☐ publication of the international application (Rule 12.4)
  - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ the international application as originally filed/furnished
- ☐ the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

nos. \_\_\_\_\_ as originally filed/furnished

nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

sheets \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (specify): \_\_\_\_\_

☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (specify): \_\_\_\_\_

☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-13

because:

☒ the said international application, or the said claims Nos. 1-13

relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 1 to 13 set forth inventions which are related to methods for the treatment of the human body.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-13

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/000957

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 16-19

YES

Claims 14, 15

NO

Inventive step (IS)

Claims

YES

Claims 14-19

NO

Industrial applicability (IA)

Claims

14-19

YES

Claims

NO

## 2. Citations and explanations (Rule 70.7)

Document 1: J. Exp. Med., Vol. 193, No. 9, pp. 1005 to 1014, 2001

Document 2: Cell, Vol. 102, No. 2, pp. 199 to 209, 2000

Document 3: WO 02/100441 A2 (Dnavec Res. Inc.), 19 December 2002

Document 4: WO 97/27310 A1 (Oxford Biomedica UK Ltd.), 31 July 1997, & EP 880594 A1 & JP 2000-500986 A

Claims 14 and 15

The inventions that are set forth in claims 14 and 15 lack novelty and do not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

Document 1 discloses hematopoietic stem cells which have been genetically modified by means of an adenovirus vector that codes angioipoietin-1. In addition, document 2 discloses mesenchymal stem cells which express angioipoietin-1, and indicates that it is possible to use these mesenchymal stem cells in the treatment of ischemia.

Claims 16, 18 and 19

The inventions that are set forth in claims 16, 18

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

and 19 do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Document 3 discloses the feature of using a minus strand RNA virus vector from a Sendai virus vector or the like as the virus vector that codes angioipoietin-1.

## Claim 17

The invention that is set forth in claim 17 does not involve an inventive step in the light of documents 1 to 4 cited in the international search report.

Document 4 discloses gene therapy wherein transformed cells, which have been transformed in vitro by using a virus vector in order to introduce a foreign gene thereto, are re-introduced into the body of a patient. Therefore, it would be obvious to a person skilled in the art to conceive of treating ischemia by using hematopoietic stem cells into which a gene that codes angioipoietin-1 has been introduced.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed
    - ☒ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."